UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Docket No. 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO: ALL CASES	

NON-PARTY THE VANDERBILT UNIVERSITY'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO QUASH SUBPOENA FOR DEPOSITION BY WRITTEN QUESTIONS

Non-Party The Vanderbilt University ("Vanderbilt") submits this Memorandum of Law in Support of its Motion to Quash Subpoena for Deposition by Written Questions (the "Subpoena") issued to the "Vanderbilt Medical Center Clinic Pharmacy" by Defendants Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates, Premier Orthopaedic Associates Surgical Center, LLC, Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith- Martin, M.D., Thomas Dwyer, M.D., Rhaul Shah, M.D., John Catalano, M.D., Richard C. DiVerniero, M.D., and Richard Strauss, M.D. (collectively, the "Premier Defendants").

SUMMARY OF THE ARGUMENT

The Subpoena calls for Vanderbilt's pharmacies to answer myriad written questions about the "due diligence" it performed before purchasing medication from New England Compounding Pharmacy, Inc. ("NECC"). Vanderbilt moves to quash the Subpoena because the information sought is irrelevant to any claims or defenses in the MDL. Vanderbilt's pharmacies never purchased methyl prednisolone acetate ("MPA"), the core product at issue in this MDL,

from NECC. Accordingly, the Premier Defendants' entire theory of relevance, upon which the Court predicated its order permitting the discovery to proceed, is nullified. Moreover, the discovery sought would not aid the jury in ascertaining the standard of care applicable to the negligence claims against the Premier Defendants where: (a) the only medication Vanderbilt ever purchased from NECC is a topical antiseptic with the brand name Betadine®, for which Vanderbilt placed only one order; (b) the standard of care cannot be established without expert testimony; (c) such expert testimony must be sufficient for a jury to find that the consensus of the profession involved recognizes the standard defined by the expert; and (d) the conduct of Vanderbilt, even when considered with that of the relatively small number of other non-party entities on whom virtually identical subpoenas were served, says nothing about the consensus of the profession involved and thus cannot reliably bolster or refute any expert testimony.

Alternatively, even if there were any relevance, which there is not, the discovery sought is disproportionate to the needs of the MDL, considering the importance of the discovery in resolving the issues and the burden imposed on Vanderbilt weighed against the likely benefit to the Premier Defendants.

Accordingly, as discussed more fully below, the Subpoena should be quashed.

BACKGROUND

A. The MDL and the Subpoena

This MDL involves wrongful death and personal injury claims arising out of the administration of MPA manufactured by NECC. *See In re New England Compounding Pharmacy, Inc. Products Liab. Litig.*, No. MDL 13–2419, 2013 WL 6058483, at *1 (D. Mass. Nov. 13, 2013) (ECF No. 572). In October 2015, the Premier Defendants issued subpoenas to ten non-party entities, including the "Vanderbilt Medical Center Clinic Pharmacy," calling for

depositions by written questions.[1] *See* Notice of Filing of Notices of Dep. by Written Questions, October 15, 2015, ECF No. 2333. Also in October 2015, another group of defendants in the MDL, Box Hill Surgery Center, LLC, Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC (collectively, the "Box Hill Defendants") issued subpoenas to ten other non-party entities. *See* Notice of Filing of Notices of Dep. by Written Questions, October 12, 2015, ECF No. 2319. The subpoenas served by the Premier Defendants and Box Hill Defendants were substantively identical and directed to a variety of orthopedic practices, surgical centers, medical centers, and other health care providers.

After the Plaintiffs' Steering Committee ("PSC") filed motions for protective orders seeking to require the depositions to be conducted orally rather than by written questions, the Premier Defendants filed a brief in which they explained why they had served these subpoenas: they were seeking "information about the due diligence conducted by these entities which formed the informational basis for their decision to purchase MPA from NECC." Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, et al's Opp'n to the Pl. Steering Committee's Mot. for Protective Order Regarding Premier's Notices of Dep. by Written Question, at 1, Nov. 6, 2015, ECF No. 2385 (emphasis added). They argued that their "goal" was to "gather targeted information as to the due diligence conducted by other NECC customers who purchased MPA," and that the "questions submitted to these entities are worded

[1] The "Vanderbilt Medical Center Clinic Pharmacy" is not a legal entity. *See* Affidavit of Frank N. Gaeta ("Gaeta Aff."), filed herewith, ¶ 2. Vanderbilt, a Tennessee not-for-profit corporation, conducts its activities through various unincorporated internal operating divisions and units, including Vanderbilt University Medical Center and seven pharmacies associated with Vanderbilt University Medical Center. *Id; see also* Affidavit of Mark Sullivan ("Sullivan Aff."), filed herewith, ¶ 2-3. Notwithstanding the misnaming of the witness, Vanderbilt construes the Subpoena as having been issued to Vanderbilt and requesting information from Vanderbilt's pharmacies.

to focus narrowly on this issue and no other, and gather as much information as possible." *Id*. at 6 (emphasis added). In their opposition to the PSC's motion for a protective order, the Box Hill Defendants expressly adopted all of the arguments made by the Premier Defendants. *See* The Box Hill Defs.' Opp'n to the Pl. Steering Committee's Mot. for Protective Order Regarding Box Hill's Notices of Dep. by Written Question, at 3, Nov. 20, 2015, ECF No. 2425. Like the Premier Defendants, the Box Hill Defendants represented to the Court that the entities on which they had served subpoenas had purchased MPA from NECC. *Id.* ("The Premier Defendants also filed notices of Depositions by Written Questions in mid-October, 2015, and served the same and subpoenas on ten different non-party entities, which had also previously purchased MPA from NECC before the meningitis outbreak.") (emphasis added).

The Court denied the PSC's motions because the subpoenas "appear to be targeted to the narrow topic of what due diligence was conducted by various NECC customers prior to purchasing MPA from NECC." Order on PSC's Mot. for Protective Order Regarding Notices of Dep. by Written Questions, at 2, Dec. 18, 2015, ECF No. 2528 (the "2015 Order") (emphasis added).

In February 2016, the Premier Defendants and Box Hill Defendants re-issued the subpoenas to many but not all of the non-party entities on whom they had served subpoenas in October 2015. Notice of Filing of Notices of Dep. by Written Questions, Feb. 17, 2016, ECF No. 2665 and exhibits thereto; Notice of Filing of Amended Notices of Dep. by Written Questions, Feb. 19, 2016, ECF No. 2669 and exhibits thereto. The Premier Defendants later withdrew their subpoena to one of those entities, Summit Surgery Center ("Summit"), in the face of Summit's motion to quash. *See* Notice of Withdrawal of Subpoena, Mar. 15, 2016, ECF No.

2746. Altogether, the Premier Defendants and Box Hill Defendants have issued and maintained subpoenas directed to 15 entities, including Vanderbilt (collectively, the "Non-Party Entities").

The Subpoena to Vanderbilt, like the subpoenas served on the other Non-Party Entities, instructs Vanderbilt to designate one or more corporate representatives of its pharmacies to answer 21 questions relating to what the pharmacies purchased from NECC; what actions the pharmacies took prior to making purchases from NECC; whether the pharmacies received any representations from Medical Sales Management and/or NECC prior to making purchases from NECC and whether the pharmacies did anything in response to those representations; and whether any patients were injured by products sold by NECC. *See* Notice of Filing of Notices of Dep. by Written Questions, Feb. 17, 2016, ECF No. 2665, and Exhibit 5 thereto, ECF No. 2665-5. The Subpoena is also accompanied by an additional 198 cross-examination questions submitted by the PSC. *Id*. The majority of these questions relate to whether anyone associated with Vanderbilt's pharmacies between January 1, 2010 and September 25, 2012, had knowledge about a variety of instances of contaminated products sold by compounding pharmacies. *Id.*

B. Vanderbilt

Non-party Vanderbilt is a private, not-for-profit research university and medical center located in Nashville, Tennessee. *See* Gaeta Aff., ¶ 2. Vanderbilt's healthcare operations consist of several hospitals and clinics, including seven pharmacies licensed by the State of Tennessee at 15 different locations. *See* Sullivan Aff., ¶ 3. The pharmacy operations employ 500 persons, dispense 21,000 doses of medications per day, and purchase approximately $275,000,000 in pharmaceuticals per year. *Id*. Vanderbilt has no affiliation with the Premier Defendants. *Id.*, ¶ 6.

Vanderbilt's pharmacies never purchased MPA from NECC. *Id.*, ¶ 4; *see also* NECC

Customer List Since 5/21/2012, Sorted by Customer - With Product Information (Oct. 23, 2012), http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325466.pdf. The only medication Vanderbilt's pharmacies ever purchased from NECC is a topical antiseptic with the brand name Betadine®, for which Vanderbilt placed only one order. *See* Sullivan Aff., ¶ 5.

C. Customers of NECC and Other Compounding Pharmacies

NECC has identified approximately 3,000 customers for the period between May 21, 2012 and October 23, 2012. *See* NECC Customer List Since 5/21/2012, Sorted by State (Oct. 23, 2012) (listing approximately 3,000 customers) http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325466.pdf. NECC was only one of thousands of compounding pharmacies in the United States at that time. *See* Sarah Turk, "Compounding Pharmacies in the U.S., IBISWorld Industry Report," at 30, (January 2015), attached to the Gaeta Aff. as Ex. A.

ARGUMENT

A. Legal Standard

The Subpoena seeks discovery from Vanderbilt's pharmacies under Fed. R. Civ. P. 30(b)(6) and 31, and was served on Vanderbilt pursuant to Rule 45. See Fed. R. Civ. P. 30(a)(1) and 31(a)(1). A Rule 45 subpoena is enforceable only if the information sought falls within the scope of proper discovery under Fed. R. Civ. P. 26(b)(1). *See In re New England Compounding Pharmacy*, No. MDL 13–2419, 2013 WL 6058483, at *4. Rule 26(b)(l), as recently amended, provides that the information sought must be not only "relevant to any party's claim or defense" but also "proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the

burden or expense of the proposed discovery outweighs its likely benefit." *See* Fed. R. Civ. P. 26(b)(l).

The amended Rule 26 is "intended to encourage judges to be more aggressive in identifying and discouraging discovery overuse." *See Henry v. Morgan's Hotel Grp., Inc.*, 2016 WL 303114, at *3 (S.D.N.Y. Jan. 25, 2016), (citing Fed.R.Civ.P. 26(b)(1) Advisory Committee's notes to 2015 amendments). "The party issuing the subpoena has the burden of establishing that the requested information is relevant to its claims or defenses." *Enargy Power (Shenzhen) Co. v. Xiaolong Wang*, 2014 WL 2048416, at *2 (D. Mass. May 16, 2014).

Non-parties such as Vanderbilt are afforded more protection from discovery than parties participating in the litigation. *See, e.g., Cusumano v. Microsoft Corp.*, 162 F.3d 708, 717 (1st Cir. 1998) ("Although discovery is by definition invasive, parties to a law suit must accept its travails as a natural concomitant of modern civil litigation. Non-parties have a different set of expectations."); *In re Centrix Fin., LLC*, 2012 WL 6625920, at *16 (D.N.J. Dec. 18, 2012) ("Everest is a non-party and therefore is afforded greater protection from discovery than a normal party."). A subpoena seeking irrelevant information from a non-party will be quashed pursuant to Rule 45(d)(3). *See In re New England Compounding Pharmacy*, No. MDL 13–2419, 2013 WL 6058483, at *10.

B. The Subpoena Must Be Quashed Because The Information Sought is Irrelevant.

The information sought through the Subpoena is irrelevant because Vanderbilt's pharmacies did not purchase MPA, and because the conduct of Vanderbilt, even when considered with that of the other Non-Party Entities, cannot reliably support or refute the expert testimony necessary to establish the applicable standard of care.

1. The Premier Defendants' Entire Theory of Relevance, Upon Which the 2015 Order is Based, is Negated Because Vanderbilt's Pharmacies Never Purchased MPA.

The Subpoena must be quashed because Vanderbilt's pharmacies did not purchase MPA and therefore, as effectively conceded by the Premier Defendants, cannot provide any relevant information. The Premier Defendants opposed the PSC's request for a protective order and sought to justify the subpoenas they issued on the basis that the subpoenas had been served on "non-party entities which had purchased MPA from NECC prior to the outbreak" and that they were seeking "targeted information as to the due diligence conducted by other NECC customers who purchased MPA." Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, et al's Opp'n to the Pl. Steering Committee's Mot. for Protective Order Regarding Premier's Notices of Dep. by Written Question, at 1, 6, Nov. 6, 2015, ECF No. 2385 (emphasis added). Because Vanderbilt's pharmacies did not purchase MPA from NECC, the Premier Defendants cannot now credibly claim that Vanderbilt possesses relevant information. The Subpoena should be quashed as a result.

Moreover, the Court's Orders have highlighted the centrality of MPA to the MDL in general and the subpoenas issued by the Premier Defendants in particular. In a 2013 order on motions to quash, the Court stated: "This litigation involves claims for wrongful death and personal injury arising out of the administration of an injectable steroid, [MPA], manufactured by defendant [NECC]." *See In re New England Compounding Pharmacy*, No. MDL 13–2419, 2013 WL 6058483, at *1. The Court further highlighted the significance of MPA in the 2015 Order. The Court denied the PSC's motions precisely because the subpoenas were targeted to the "narrow topic of what due diligence was conducted by various NECC customers prior to purchasing MPA from NECC." *See* 2015 Order, at 2 (emphasis added). Because the only

relevant area of inquiry recognized by the Court in the 2015 Order does not apply to Vanderbilt, an entity that never purchased MPA, the Subpoena should be quashed.

2. The Conduct of Vanderbilt's Pharmacies is Irrelevant to Determining the Standard of Care.

The apparent purpose of the Premier Defendants and Box Hill Defendants for seeking this discovery is to establish the standard of care applicable to the negligence claims against them. *See generally* The Box Hill Defs.' Opp'n to the Pl. Steering Committee's Mot. for Protective Order Regarding Box Hill's Notices of Dep. by Written Question, at 2, Nov. 20, 2015, ECF No. 2425 ("[T]he PSC contends that the Box Hill Defendants failed to engage in sufficient 'due diligence' allegedly required by the standard of care, and that that failure caused the Box Hill Defendants to purchase contaminated MPA from NECC, which then allegedly caused injury to the Plaintiffs in the instant cases."). Even if the Premier Defendants were permitted to reverse course, despite their prior representations to this Court, and argue that the due diligence conducted by buyers of any NECC products is sufficiently relevant to the standard of care to justify the Subpoena, their argument would fall short. The only medication Vanderbilt ever purchased from NECC is Betadine, a topical antiseptic, for which Vanderbilt placed only one order. The due diligence performed by Vanderbilt before buying a topical antiseptic does not have any meaningful relevance to the standard of care applicable to the purchase of MPA, an injectable steroid.

Furthermore, the testimony of Vanderbilt and the other Non-Party Entities is irrelevant because the standard of care cannot be established without expert testimony, whether or not the negligence claims against the Premier Defendants qualify as medical malpractice claims. *See*

Davis v. Brickman Landscaping, Ltd., 98 A.3d 1173, 1179-80 (N.J. 2014).[2] In *Davis*, the court noted that, "when deciding whether expert testimony is necessary, a court properly considers whether the matter to be dealt with is so esoteric that jurors of common judgment and experience cannot form a valid judgment as to whether the conduct of the [defendant] was reasonable." *Id.* at 1179 (internal quotation marks omitted). As examples of cases requiring the plaintiff to advance expert testimony establishing an accepted standard of care, the *Davis* decision lists "the ordinary dental or medical malpractice case," … "the responsibilities and functions of real-estate brokers with respect to open-house tours," … "precautions necessary to ensure the safe conduct of a funeral procession," … "the appropriate conduct for those teaching karate," [and] "the proper repair and inspection of an automobile." *Id.* at 1179 (internal quotation marks omitted). The court concluded, based on this precedent, that the plaintiffs were required to present expert testimony to establish the standard of care applicable to the inspection of fire sprinklers by qualified contractors. *See Id*. at 1180. A review of the myriad questions put to Vanderbilt's pharmacies by the Premier Defendants and the PSC demonstrates that matter at hand is sufficiently esoteric as to require expert testimony.

Also, such expert testimony must be sufficient for a jury to find that the consensus of the profession or industry involved recognizes the standard defined by the expert. *See Taylor v. DeLosso*, 725 A.2d 51, 53-54 (N.J. Super. Ct. App. Div. 1999) ("[O]pinion testimony must relate to generally accepted … standards, not merely to standards personal to the witness. In other words, plaintiff must produce expert testimony upon which the jury could find that the consensus

[2] The Premier Defendants are located in New Jersey and have been sued by a number of residents of New Jersey alleging to have been injured in New Jersey. *See generally* Conditional Transfer Order, February 22, 2013, ECF No. 129 and complaints in New Jersey lawsuits listed therein. Accordingly, New Jersey law must apply to the negligence claims against the Premier Defendants.

of the particular profession involved recognized the existence of the standard defined by the expert.") (citations and internal quotation marks omitted).

For medical malpractice cases, New Jersey law appears to treat proof of the consensus of medical opinion, through expert testimony, as dispositive of the issue of the standard of care. *See Fernandez v. Baruch*, 244 A.2d 109, 112 (N.J. 1968). In *Fernandez*, a wrongful death action against psychiatrists, the "basic question [was] whether the defendant doctors, in the application of accepted medical practice, knew or should have known that [the plaintiff] presented a suicide risk requiring special precautions." *Id*. at 111. The "plaintiff failed to produce evidence upon which the jury could find that the consensus of medical opinion required that the defendant doctors envision a suicide potential …." *Id*. at 112. Accordingly, the court ruled that the defendants could not be liable for malpractice because "there was no proof that generally accepted medical standards required the defendant doctors to conclude that [the plaintiff] was likely to attempt suicide…." *Id*. For other negligence claims where the standard of care must be established through expert testimony, "[e]vidence of the custom or practice of a particular industry does not conclusively dispose of the issue of the proper standard of conduct." *Estate of Elkerson v. N. Jersey Blood Ctr.*, 776 A.2d 244, 250 (N.J. Super. App. Div. 2001). It is "at most evidential of this standard." *Davis*, 98 A.3d at 1182 (citation omitted). In any event, the conduct of a relatively small number of members of the profession or industry involved is no substitute for expert testimony.

The testimony sought from Vanderbilt, even when considered with that sought from the other Non-Party Entities, would not even be of value to supplement any expert testimony offered by the Premier Defendants. That is because the conduct of Vanderbilt and the other Non-Party Entities in their decisions to purchase from NECC says nothing about the consensus of the

profession or industry involved, which must be proved to establish the standard of care. Vanderbilt and the other Non-Party Entities consist of 15 buyers of medications from NECC. NECC, however, has listed approximately 3,000 customers for 2012, the year in which it sold the tainted MPA. Also, NECC was only one of thousands of compounding pharmacies in the United States at that time. Vanderbilt and the other Non-Party Entities simply do not provide a sufficient sample size upon which any reliable inferences or conclusions could be drawn.

C. Alternatively, The Subpoena Must Be Quashed Because The Discovery Sought is Disproportionate To the Needs of the MDL.

Even if there were some relevance to the discovery sought pursuant to the Subpoena, it would be disproportionate to the needs of the MDL, considering the importance of the discovery in resolving the issues and the burden imposed on Vanderbilt weighed against the likely benefit to the Premier Defendants. The Subpoena constitutes exactly the type of "discovery overuse" that the recent revisions to Rule 26(b)(l) are designed to prevent. The Subpoena would impose a considerable and unnecessary burden on Vanderbilt. In order to answer the 219 questions posed pursuant to the Subpoena (21 by the Premier Defendants and 198 by the PSC), Vanderbilt would have to undertake significant efforts to research and answer these questions. *See* Sullivan Aff., ¶ 7. Indeed, to answer many questions regarding the state of "Vanderbilt Medical Center Clinic Pharmacy's" knowledge, Vanderbilt would have to undertake surveys or interviews to determine what numerous employees did or did not know. Moreover, the questions all relate to facts that took place more than four years ago. Answering these questions therefore requires overcoming the challenges presented by the passage of time, including documents being more difficult to locate, recollections fading, and personnel turnover. Vanderbilt would also have to expend resources to prepare one or more witnesses to testify.

By contrast, Vanderbilt's pharmacies did not purchase MPA from NECC, but instead

purchased only a topical antiseptic, and the establishment of the standard of care requires expert testimony on the consensus of the profession involved, of which Vanderbilt and the other Non-Party Defendants represent only a handful of the thousands of members. The burden imposed on Vanderbilt to comply with the Subpoena would thus be significantly outweighed by any infinitesimally small benefit that could come from information provided by Vanderbilt. *See* Fed. R. Civ. P. 26(b)(l).

CONCLUSION

For the foregoing reasons, Vanderbilt respectfully requests this Court to quash the subpoena issued to it by the Premier Defendants.

Respectfully submitted,

THE VANDERBILT UNIVERSITY

By its attorneys,

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Dated: April 1, 2016

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing, and paper or electronic copies will be delivered to those indicated as non-registered participants on April 1, 2016.

/s/ Frank N. Gaeta
Frank N. Gaeta